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10/796,578	03/08/2004	Clark R. Baker JR.	009103-022700US	1111

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EXAMINER	
TSAI, CAROL S W	

ART UNIT	PAPER NUMBER
2857	

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

H.A

Office Action Summary	Application No.	Applicant(s)	
	10/796,578	BAKER, CLARK R.	
	Examiner	Art Unit	
	Carol S. Tsai	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11,17 and 18* is/are allowed.

6)☒ Claim(s) *1,5-7, and 12-16* is/are rejected.

7)☒ Claim(s) *2-4 and 8-10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5, 6, and 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are:

"a first ensemble averager" should read - - a first ensemble averager averaging said waveforms. The omitted elements are: averaging said waveforms.

"a second ensemble averager" should read - - a second ensemble averager averaging said normalized waveforms . The omitted elements are: averaging said normalized waveforms.

4. Claims 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are:

"a first low pass filtering" should read - - a first low pass filter filtering said waveforms. The omitted elements are: a first low pass filter filtering said waveforms.

"a second low pass filter" should read - - a second low pass filter filtering said normalized waveforms. The omitted elements are: filtering said normalized waveforms.

5. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are:

"a first low pass filtering and ensemble averager" should read - - a first low pass filter filtering said waveforms and ensemble averager averaging said waveforms. The omitted elements are: a first low pass filter filtering said waveforms and averaging said waveforms.

"a second low pass filter and ensemble averager" should read - - a second low pass filter filtering said waveforms and ensemble averager averaging said normalized waveforms. The omitted elements are: filtering said waveforms and averaging said normalized waveforms.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over U. S. Patent No. 4,960,1126 to Conlon et al. in view of U. S. Patent No. 4,407,290 to Wilber and U. S. Publication 2002/0151812 to Scheiner et al.

With respect to claims 1 and 5, Conlon et al. disclose a method for processing signals in a pulse oximeter to determine oxygen saturation and pulse rate, comprising: receiving waveforms corresponding to two different wavelengths of light from a patient (see col. 2, lines 36-39 and col. 3, lines 51-55); ensemble averaging said waveforms in a ensemble averager (see col. 8, lines 51-59); calculating a pulse rate based on an output of said ensemble averager (see col. 9, lines 61-63).

Conlon et al. do not disclose normalizing said waveforms to produce normalized waveforms.

Wilber teaches normalizing said waveforms to produce normalized waveforms (see col. 2, lines 6-15 and col. 4, lines 19-42).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Conlon et al.'s method to include normalizing said waveforms to produce normalized waveforms, as taught by Wilber, in order that these offset voltages can be removed.

Conlon et al. do not disclose ensemble averaging normalized waveforms in said ensemble averager.

It is, however, considered inherent that Conlon et al. ensemble averages normalized waveforms (see col. 2, lines 45-51), because such averaging is known to be a necessary step in order that the noise associated with the process can be filtered and the input signal can be reconstructed.

Conlon et al. in combination with Wilber do not disclose a first ensemble averager and a second esnemble averager respectively.

Scheiner et al. teach a first ensemble averager (ensemble averager 412 shown on Fig. 4) and a second ensemble averager (ensemble averager 430 shown on Fig. 4).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Conlon et al. in combination with Wilber's method to include a first ensemble averager and a second ensemble averager, as taught by Scheiner et al., in order that no normalized waveforms and normalized waveforms can be performed in separate ensemble averager in order to filter noise associated with the process and reconstruct the input signal respectively.

Wilber does not disclose expressly calculating an oxygen saturation based on an output of said second ensemble averager, but it is considered inherent, because such calculating is known to be a necessary step because a typical pulse oximeter measures two physiological parameters, percent oxygen saturation of arterial blood hemoglobin and pulse rate.

8. Claims 7 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U. S. Patent No. 6,035,223 to Baker, Jr. in view of U. S. Patent No. 4,407,290 to Wilber.

With respect to claims 7 and 12, Baker, Jr. disclose a method for processing signals in a pulse oximeter to determine oxygen saturation and pulse rate, comprising: receiving waveforms corresponding to two different wavelengths of light from a patient (see col. 1, lines 22-27); low pass filtering said waveforms in a first low pass filter (see col. 3, line 27).

Baker, Jr. does not disclose expressly calculating a pulse rate based on an output of said first low pass filter, but it is considered inherent, because such calculating is known to be a necessary step because a typical pulse oximeter measures two physiological parameters, percent

oxygen saturation of arterial blood hemoglobin and pulse rate.

Baker, Jr. also disclose normalizing said waveforms to produce normalized waveforms (see col. 3, lines 27-32).

Baker, Jr. does not disclose low pass filtering said normalized waveforms in said low pass filter.

It is, however, considered inherent that Baker, Jr. filters said normalized waveforms in said low pass filter (see col. 2, lines 45-51), because such filtering is known to be a necessary step in order that the DC voltage supplied by generator from the input signal can be subtracted to produce an output signal that is essentially an AC component on a zero reference level.

Baker, Jr. does not disclose a first low pass filter and a second low pass filter.

Wilber discloses a first low pass filter and a second low pass filter (low pass filter 57 and 58 shown on Fig. 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Baker, Jr.'s method to include a first low pass filter and a second low pass filter, as taught by Wilber, because no normalized waveforms and normalized waveforms can be performed in separate low pass filter in order the DC voltage supplied by generator from the input signal can be subtracted to produce an output signal that is essentially an AC component on a zero reference level respectively.

Wilber does not disclose expressly calculating an oxygen saturation based on an output of said second low pass filter, but it is considered inherent, because such calculating is known to be a necessary step because a typical pulse oximeter measures two physiological parameters, percent oxygen saturation of arterial blood hemoglobin and pulse rate.

Allowable Subject Matter

9. Claims 2-4 and 8-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 6 and 13-15 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. Claim 16 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

12. Claims 11, 17, and 18 are allowed.

13. The following is a statement of reasons for the indication of allowable subject matter:

U. S. Patent No. 4,960,1126 to Conlon et al. in view of U. S. Patent No. 4,407,290 to Wilber, U. S. Publication 2002/0151812 to Scheiner et al., and U. S. Patent No. 6,035,223 to Baker, Jr. are references closest to the claimed invention. Conlon et al. in combination with Wilber and Scheiner et al. disclose a method for processing signals in a pulse oximeter to determine oxygen saturation and pulse rate, comprising: receiving waveforms corresponding to two different wavelengths of light from a patient; ensemble averaging said waveforms in a first ensemble averager; calculating a pulse rate based on an output of said ensemble averager; normalizing said waveforms to produce normalized waveforms; ensemble averaging normalized waveforms in a second ensemble averager; and calculating an oxygen saturation based on an output of said second ensemble averager. Baker, Jr. in combination with Wilber disclose a method for processing signals in a pulse oximeter to determine oxygen saturation and pulse rate,

comprising: receiving waveforms corresponding to two different wavelengths of light from a patient; low pass filtering said waveforms in a first low pass filter; calculating a pulse rate based on an output of said first low pass filter; normalizing said waveforms to produce normalized waveforms; low pass filtering said normalized waveforms in a second low pass tilter; and calculating an oxygen saturation based on an output of said second low pass. However, Conlon et al. in combination with Wilber, Scheiner et al., and Baker, Jr. do not teach a method for processing signals in a pulse oximeter to determine oxygen saturation and pulse rate, comprising: receiving waveforms corresponding to two different wavelengths of light from a patient; low pass filtering and ensemble averaging said waveforms in a first low pass filter and ensemble averager; calculating a pulse rate based on an output of said first low pass filter and ensemble averager; normalizing said waveforms to produce normalized waveforms; low pass filtering and ensemble averaging said normalized waveforms in a second low pass filter and ensemble averager; and calculating an oxygen saturation based on an output of said second low pass filter and ensemble averager.; and including all of the other limitations in the respective independent claims.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Goodman et al. disclose a method and apparatus for measuring and correlating a patient's heart activity with optical detection of the patient's blood flow.

Baker, Jr. discloses an improved method and apparatus for more accurately calculating

and measuring vital information such as oxygen saturation and pulse rate when an ECG signal is not available.

Jacques discloses a method for determining an arterial blood oxygen saturation level according to this invention includes measuring the light transmittance through tissue of light of a first wavelength and a second wavelength.

Kimball discloses a technique to compensate for, or eliminate, motion-induced artifacts in patient-attached critical care monitoring instruments.

Ali et al. disclose a pulse oximeter has an integrated mode in which it operates as a plug-in module for a multiparameter patient monitoring system.

Mendelson discloses a sensor for use in an optical measurement device and a method for non-invasive measurement of a blood parameter.

Reuss discloses an improved pulse oximeter (sensor and monitor) using a plurality of wavelengths selected to provide sensitivity to both oxygen saturation and deviations in tissue site characteristic(s) from conditions at calibration.

Contact Information

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carol S. W. Tsai whose telephone number is (571) 272-2224. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on (571) 272-2216. The fax number for TC 2800 is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be

directed to the TC 2800 receptionist whose telephone number is (571) 272-1585 or (571) 272-2800.

In order to reduce pendency and avoid potential delays, Group 2800 is encouraging FAXing of responses to Office actions directly into the Group at (703) 872-9306. This practice may be used for filing papers not requiring a fee. It may also be used for filing papers which require a fee by applicants who authorize charges to a PTO deposit account. Please identify the examiner and art unit at the top of your cover sheet. Papers submitted via FAX into Group 2800 will be promptly forwarded to the examiner.

Carol S. W. Tsai
Primary Examiner
Art Unit 2857

04/07/05